

1645

Patent
Attorney's Docket No. 032905-010

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Kevin C. Hazen *et al.*

Application No.: 09/913,850

Filed: December 14, 2001

For: YEAST CELL WALL PEPTIDES AND
ANTIBODIES THERETO

)
)
) Group Art Unit: 1645

) Examiner: Robert A. Zeman

) Confirmation No.: 5481

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TECH CENTER 1600/2900

RESPONSE TO RESTRICTION REQUIREMENT TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Enclosed is a Response to Restriction Requirement for the above-identified patent application.

☐ A Petition for Extension of Time is also enclosed.

☐ A Terminal Disclaimer and the ☐ \$55.00 (2814) ☐ \$110.00 (1814) fee due under 37 C.F.R. § 1.20(d) are also enclosed.

☐ Also enclosed is/are _____.

☒ Small entity status is hereby claimed.

☐ Applicant(s) requests continued examination under 37 C.F.R. § 1.114 and enclose the ☐ \$385.00 (2801) ☐ \$770.00 (1801) fee due under 37 C.F.R. § 1.17(e).

☐ Applicant(s) requests that any previously unentered after final amendments not be entered. Continued examination is requested based on the enclosed documents identified above.

☐ Applicant(s) previously submitted ___, on ___, for which continued examination is requested.

☐ Applicant(s) requests suspension of action by the Office until at least ___, which does not exceed three months from the filing of this RCE, in accordance with 37 C.F.R. § 1.103(c). The required fee under 37 C.F.R. § 1.17(i) is enclosed.

Response to Restriction Requirement Transmittal Letter

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☐ A Request for Entry and Consideration of Submission under 37 C.F.R. § 1.129(a) (1809/2809) is also enclosed.

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☒ No additional claim fee is required.

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☐ An additional claim fee is required, and is calculated as shown below:

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AMENDED CLAIMS					
	NO. OF CLAIMS	HIGHEST NO. OF CLAIMS PREVIOUSLY PAID FOR	EXTRA CLAIMS	RATE	ADD'L FEE
Total Claims	48	MINUS 48 =	0	× \$18.00 (1202) =	0.00
Independent Claims	8	MINUS 8 =	0	× \$86.00 (1201) =	0.00
If Amendment adds multiple dependent claims, add \$290.00 (1203)					
Total Claim Amendment Fee					0.00
If small entity status is claimed, subtract 50% of Total Claim Amendment Fee					
TOTAL ADDITIONAL CLAIM FEE DUE FOR THIS AMENDMENT					0.00

☐ A total fee in the amount of \$ _____ is enclosed.

☐ Charge \$ _____ to Deposit Account No. 02-4800.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17, 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: November 4, 2003

By


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(10/03)



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RESPONSE TO RESTRICTION REQUIREMENT

TECH CENTER 1600/2900

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This paper is in complete response to the restriction requirement set forth in the Official Action mailed October 6, 2003 (Paper No. 5). The Office Action sets forth a one-month period of time in which to reply. Accordingly, this election is being submitted on or before the current due date of November 6, 2003.

In the Office Action, the Examiner sets forth a restriction requirement among sixteen groups of claims as summarized below:

Group I: Claims 1-7, drawn to peptides with a general formula of G-X₁-X₂-R

Group II: Claims 8-13, drawn to antibodies to peptides with the general formula of G-X₁-X₂-R and cells producing said antibodies.

Group III: Claim 14, drawn to methods of treating a yeast infection in a patient using antibodies to peptides with the general formula of G-X₁-X₂-R.

Group IV: Claims 15-17, drawn to drawn to methods of detecting a hydrophobic binding domain using antibodies peptides with the general formula of G-X₁-X₂-R.

- Group V:** Claim 18, drawn to methods of isolating hydrophobic binding domain using antibodies to peptides with the general formula of $G-X_1-X_2-R$.
- Group VI:** Claims 19-23, drawn to methods of treating a yeast infection using peptides with the general formula $G-X_1-X_2-R$.
- Group VII:** Claims 24-25, drawn to peptides with the general formula $E-X_1-L-X_2-X_3-X_4$.
- Group VIII:** Claims 26-31, drawn to antibodies to peptides with the general formula of $E-X_1-L-X_2-X_3-X_4$ and cells producing said antibodies.
- Group IX:** Claim 32, drawn to methods of treating a yeast infection in a patient using antibodies to peptides with the general formula $E-X_1-L-X_2-X_3-X_4$.
- Group X:** Claims 33-35, drawn to drawn to methods of detecting a hydrophobic binding domain using antibodies peptides with the general formula $E-X_1-L-X_2-X_3-X_4$.
- Group XI:** Claim 36, drawn to methods of isolating hydrophobic binding domain using antibodies to peptides with the general formula of $E-X_1-L-X_2-X_3-X_4$.
- Group XII:** Claims 37-40, drawn to methods of treating a yeast infection using peptides with the general formula $E-X_1-L-X_2-X_3-X_4$.
- Group XIII:** Claims 41-43, drawn to antibodies produced by cell line F6-5F8-E10 and cell lines.
- Group XIV:** Claim 44, drawn to methods of treating a yeast infection in a patient using antibodies produced by cell line F6-5F8-E10.
- Group XV:** Claims 45-47, drawn to drawn to methods of detecting a hydrophobic binding domain using antibodies produced by cell line F6-5F8-E10.
- Group XVI:** Claim 48, drawn to methods of isolating hydrophobic binding domain using antibodies produced by cell line F6-5F8-E10.

Applicants respectfully *traverse* the restriction requirement as set forth in the Office Action.

Under MPEP § 803, a restriction is proper if the subject matter can be restricted into one of two or more claimed inventions. Inventions must be either independent (MPEP § 806.04) or distinct (MPEP § 806.05). However, the second element for a restriction requirement to be proper is that if the search in the examination of an entire application can be made without *serious burden*, the Examiner *must* examine it on its merits, even though the application includes claims to independent and distinct inventions.

The Office Action merely divides the claims into sixteen different groups. The Office Action does not further elaborate as to how these sixteen groups are independent or distinct, *and* how each of these sixteen different groups would cause a *serious burden* on the Examiner such that they must be separately examined. The requirement of showing that there is a *serious burden* was recently emphasized by Group Directors John Doll, Bruce Kisliuk and Jasmine Chambers on October 29, 2003 at the Biotechnology, Chemical & Pharmaceutical Customer Partnership Meeting.

Under MPEP § 816, such reasoning setting forth the basis for the restriction is required ("the particular reasons relied on by the Examiner for holding that the invention as claimed are either independent or distinct should be concisely stated. A mere statement of conclusion is inadequate."). Applicants submit that the Office has not set forth an explanation of *why* a restriction is required. Accordingly, as a proper restriction under MPEP § 803 has not been fully adduced with regard to the originally presented claims, the restriction should be withdrawn or at the very least reconsidered.

Nevertheless, to comply with the requirements of 37 C.F.R. § 1.143 and in an effort to further prosecution, Applicants *provisionally elect, with traverse*, the invention of **Group II** (*i.e.*, claims 8-13) for prosecution in the above-identified application. The reasons for the traversal and assertion that a proper restriction has not been adduced are set forth below. Also set forth are arguments why various groups should be rejoined including

why at least the claims of Group III (*i.e.*, claim 14) should be rejoined with the elected claims of Group II for examination.

First, Applicants draw the Examiner's attention to an Annex B of the Administrative Instructions under the PCT. Annex B, Example 4 details how unity of invention exists between a claim to a compound X_1 belonging to the family X, and another claim directed to a method of using a family of compounds X as insecticides. It is clear from this example that method of treatment claims combined with the compound being used in the method of treatment have unity and should be grouped together. Accordingly, the claims for at least the claims of Group II (*i.e.*, claims 8-13) and the claim of Group III (*i.e.*, claim 14 drawn to methods of treating infection in a patient using the antibodies of Group II) would have unity of invention. Accordingly Applicants respectfully request that at least the claims of Groups II and III be rejoined.

Second, for analogous reasons as discussed for Groups II and III, the claims for Group VIII (*i.e.*, claims 26-31 drawn to antibodies to peptides of the formula $E-X_1-L-X_2-X_3-X_4$ and cells producing the antibodies) and Group IX (*i.e.*, claim 32 drawn to methods of treating a yeast infection using those antibodies) should likewise be rejoined.

Third, this application is a national stage application of International PCT Application No. PCT/US 00/04228. During the examination by WIPO, the Examiner handling the International PCT application identified twelve groups and not sixteen groups. Thus, the instant Examiner has added an additional four groups in contravention to an international treaty. This is not permitted. At the very least, the original groups should have been maintained. Applicants further note that no explanation was set forth in the Official Action discussing the discrepancy in claim groups (*i.e.*, four additional groups in Paper No. 5) between the lack of unity and the instant restriction requirement.

Fourth, Applicants respectfully submit that the claims belonging to each of Groups I-VI, Groups VII-XII, Groups XIII-XVI respectively should be rejoined based on the commonality of their sequences or cell lines. As their search would be coextensive, there

would be no additional burden, let alone a serious burden, on the Examiner to search the claims of these groups.

Fifth, Applicants submit that any nominal burden placed upon the Examiner to search any of the rejoined groups to determine the art relevant to Applicants' overall invention is significantly outweighed by the public's interest in not having to obtain and study many separate patents in order to have available all of the issued patent claims covering Applicants' invention. As asserted above, a *prima facie* supporting this restriction was not addressed. Applicants further submit that the Groups of claims as discussed above are so closely related, that a proper search of any of the claims of one group, should by necessity, require a proper search of the others. Thus, Applicants submit that all of the claims can be searched simultaneously, and that a duplicate search, with possibly inconsistent results, may occur if the restriction requirement is maintained. In the course of economy, for the Office, and for the public-at-large, and for Applicants, reconsideration and withdrawal of the restriction requirement are requested.

As summarized above, Applicants assert that the restriction requirement is improper for at least all the reasons mentioned, and that no election should be made. Nevertheless, to comply with the requirements of 37 C.F.R. § 1.143 and merely in an effort to further prosecution, Applicants provisionally elect, *with traverse*, the claims of **Group II** (*i.e.*, Claims 8-13) for prosecution in the above-identified application.

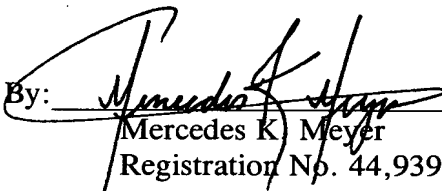
CONCLUSION

This response is believed to be in a full response to the outstanding Office Action. Should any issues remain outstanding or if there are any questions concerning this paper, or the application in general, the Examiner is invited to telephone the undersigned at the Examiner's earliest convenience. Should any fees be owed to the Office (or reimbursed to Applicants) with respect to this paper, the Office is authorized respectively to charge or refund Deposit Account No. 02-4800.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: November 4, 2003

By: 
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